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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,420	03/29/2001	Herbert B. Slade	55507USA002	5602

7590

01/02/2002

Office of Intellectual Property Counsel
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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/820,420

Applicant(s)

SLADE, HERBERT B.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

The Information Disclosure Statement filed July 2, 2001 is not currently available to the examiner. Applicant is requested to submit another copy with the response to this office action for consideration by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating or preventing dermal lesions of envenomation caused by spider, jellyfish and insect of the order Hymenoptera, does not reasonably provide enablement for method of treating or preventing dermal lesions of envenomation caused by other organisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant case, there is no adequate direction provided by the applicant as to how to treat or prevent dermal lesions caused by any other organisms in the invention. Furthermore, the instant specification does not provide any working examples to point out how dermal lesions caused by any other organisms, other than the one caused by spider, jellyfish and insect of the order Hymenoptera, can be successfully treated by the immune responsive modifier (IRM) compounds in the invention.

Moreover, it is known in the art that different medical conditions may have different etiology and/or treatment. Therefore a different dermal lesions caused by organisms other than spider, jellyfish and insect of the order Hymenoptera may require a totally different treatment. Due to this unpredictability, it would prevent the skilled artisan from treating or preventing a species of dermal lesions caused by other organisms to retain the desired therapeutic efficacy of the instant invention without undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomai et al. (WO 98/17279) and Gerster et al. (US Patent 6,110,929) in view of Bitterman-Deutsch et al. (HAREFUAH, 1990; 119(5-6):137-139), Mosbech et al. (Ugeskrift for Laeger, 1991;153(44):3067-3071), Binder (Medical Toxicology and Adverse Drug Experience, 1989;4(3):163-173), and Auerbach et al. (Journal of Emergency Medicine, 1987;5(6):487-491).

Tomai et al. teaches imidazoquinoline amine compounds including 4-amino-2-ethoxymethyl- α,α -dimethyl-1H-imidazo[4,5-c]quinoline-1-ethanol and 1-(2-

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methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine, preferred compounds herein, can inhibit T-cell Type-2 activities (See particularly the abstract, page 2, line 5-20, page 12, line 13-20, claim 17). By inhibiting the activities of T-cell Type 2, it can also reduce the production of cytokines such as interleukin-3, interleukin-4, and interleukin-5, and the production of IgE and eosinophils activities thereby (See particularly the abstract, page 2, line 5-20, page 12, line 13-20, claim 17). Tomai et al. also teaches that IgE is the important component of allergic reaction (See particularly page 12, line 13-20). Tomai et al. also teaches that the imidazoquinoline amine compounds including 4-amino-2-ethoxymethyl- α,α -dimethyl-1H-imidazo[4,5-c]quinoline-1-ethanol may be administered via topical route as topical cream or gel (See particularly page 3, line 14-15).

Gerster et al. teaches thiazoquinoline compounds including 2-methylthiazolo[4,5-c]quinolin-4-amine, 2-ethylthiazolo[4,5-c]quinolin-4-amine, 2-propylthiazolo[4,5-c]quinolin-4-amine, and 2-butylthiazolo[4,5-c]quinolin-4-amine, preferred compounds herein, can inhibit T-cell Type-2 activities and be useful in wound treatment (See particularly the abstract; col.6, line 41-46; also also col. 14, line 63-64). Gerster et al. also teaches that the thiazoquinoline compounds may be formulated into topical creams and ointments (See col. 13, line 49).

The references do not expressly teach the imidazoquinoline and thiazoquinoline compounds are useful in treating and/or preventing dermal lesions by envenomation, in particular caused by spider, jellyfish and insect of the order Hymenoptera.

Bitterman-Deutsch et al. teaches that lesions caused by brown recluse spider envenomation may be treated by dapsone, which presumably acting by reducing the activity of polymorphonuclear leukocytes (See particularly abstract).

Mosbech et al. teaches that bee or wasp sting could result in allergic reactions (See the abstract).

Binder teaches that local treatment of Black widow spider envenomations includes local wound care (See particularly abstract). Binder also teaches that Black widow spider envenomation could cause cell membrane lyses and the release of chemotaxis (See the abstract).

Auerbach et al. teaches that jellyfish envenomation could cause intense dermatitis that is responsive to local and systemic mild immunosuppressive agent corticosteroid (See the abstract).

It would have been obvious to one skill in the art when the invention was made to employ the imidazoquinoline and thiazoquinoline compounds herein in a method of treating and preventing dermal lesions by envenomation, in particular caused by spider, jellyfish and insect of the order Hymenoptera.

One of ordinary skill in the art would have motivated to employ the imidazoquinoline and thiazoquinoline compounds herein in a method of treating and preventing dermal lesions by envenomation, in particular caused by spider, jellyfish and insect of the order Hymenoptera because the imidazoquinoline and thiazoquinoline compounds herein are known to be useful in treating diseases by T-cell type 2 inhibition, esinophils (polymorphhnuclear leukocyte) inhibition, and IgE inhibition.

Therefore, employing the imidazoquinoline and thiazoquinoline compounds herein to treat or prevent dermal lesions caused by brown recluse spider or black widow spider envenomation would be reasonably expected to be effective since blocking polymorphnuclear leukocyte activities and chemotaxis is an effective treatment module for the spider envenomation. Furthermore, employing the imidazoquinoline and thiazoquinoline compounds herein to treat or prevent dermal lesions caused by jellyfish and bee envenomation would be reasonably expected to be effective since the the imidazoquinoline and thiazoquinoline compounds herein are known to be useful in blocking IgE and esinophil activities, which is an important component for allergic dermatitis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

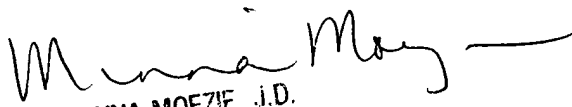
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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San-ming Hui

December 28, 2001


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